

WHAT IS CLAIMED IS:

1. A subunit of CA125 antigen having a molecular weight of about 40 kilodaltons.

2. The subunit of Claim 1 further characterized as being a subunit of tumor-associated CA125.

3. An antibody having specificity for a 40 kilodalton subunit of the antigen CA125.

4. The antibody of Claim 3 which is a monoclonal antibody.

5. ~~A method of detection of ovarian cancer which comprises the steps of contacting the serum of an individual suspected of having the cancer with at least one antibody having specificity for a 40 kilodalton subunit of CA125 and detecting a subunit-antibody reaction.~~

6. The method of Claim 5 which comprises the steps of:

P1 (a) contacting serum of a patient suspected of having ovarian cancer with a first antibody having specificity for either the 40 kilodalton subunit of CA125 or for CA125 antigen, the first antibody being bound to a solid surface, and allowing time sufficient for formation of a binary complex;

P1 (b) adding to the binary complex a second antibody having specificity either for the subunit or for CA125 antigen, the second antibody being labeled with a reporter molecule capable of giving a detectable signal, and allowing time sufficient for formation of a ternary complex, at least one of said antibodies having specificity for the 40 kilodalton subunit;

P1 (c) detecting the presence of the ternary complex by observing the detectable signal of the reporter molecule.

7. A kit for the diagnosis and monitoring of ovarian cancer, the kit containing being compartmentalized to receive:

ad (a) a first container containing an antibody having specificity for a 40 kilodalton ^{molecular weight} subunit of ^{ovarian tumor associated} CA125 antigen;

ad (b) a second container containing a second antibody having specificity for ^{serous cystadenocarcinoma ovarian tumor associated} CA125 antigen or the 40 kilodalton subunit;

40 P one of said antibodies being immobilized on a solid surface and another of said antibodies being labelled with a reporter molecule capable of giving a detectable signal.

10 8. The kit of claim 7 wherein the reporter molecule is a radioisotope, an enzyme, a fluorescent molecule, a chemiluminescent molecule or a bioluminescent molecule;

9. The kit of claim 7 wherein the reporter molecule is an enzyme.

15 10. The kit of claim 9 wherein the kit further comprises:

Q (c) a third container ~~container~~ containing a substrate for the enzyme.

20

END

25

30

27

35